MAY - 3 2000

K001057

9.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

Dave Osborn
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Healthcare Solutions Group
Agilent Technologies
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This summary was prepared on March 31, 2000.

2. The name of this device is the AIC Software Release C.0 and Agilent M2/M3/M4 Compact Portable Patient Monitor, Revision C. Classification names are as follows:

AIC

Device Panel	Classification	ProCode	Description
Panel 74 Cardiovascular	None	74 MHX	Physiological Monitor, Patient Monitor
	870.1025, III	74 DSI	Arrhythmia Detector and Alarm
	870.1025, III	74 MLD	Monitor, ST Alarm
	870.2800, II	74 DSH	Recorder, Magnetic Tape, Medical

M2/M3/M4

Device Panel	Classification	ProCode	Description
Panel 74 Cardiovascular	None	74 MHX	Physiological Monitor, Patient Monitor
	870.1025, III	74 DSI	Arrhythmia Detector and Alarm
	870.1025, III	74 MLD	Monitor, ST Alarm
	870.2350, II	74 DRW	Electrocardiograph lead switching adapter
	870.2300, II	74 DRT	Cardiac Monitor
	870.2340, II	74 FYW	Electrocardiograph
	870.1435, II	74 DXG	Computer, Diagnostic, Pre-programmed, Single Function
	870.2900, II	74 DSA	Cable, Transducer and Electrode, including Patient Connector
	870.2850, II	74 DRS	Extravascular Blood Pressure Transducer
Panel 73 Anesthesiology	868.1400, II	73 CCK	Carbon Dioxide Gas Analyzer
Panel 80 General Hospital	880.2910, II	80 FLL	Clinical Electronic Thermometer

3. The new devices are substantially equivalent to the previously cleared HP CentralVue Software device marketed pursuant to K964832, K993907, and K993171 and to the previously cleared M2/M3/M4 K971910, K981576, K990972, K991773, K992273, and K993383.

4. The modifications are a software-based changes that provide networking capability between central stations and bedside monitors.

5. The new devices have the same intended use as the legally marketed predicate devices. (AIC) They are used to display physiologic waves, parameters and, trends, to format data for compliant strip chart recorders, to format data for printed reports, and the secondary annunciation of alarms for up to 16 patients from other networked medical devices at a centralized location. To provide retrospective review of alarms, physiologic waves and parameters. And to provide primary annunciation of alarms, and configuration and control access for networked telemetry monitors at a centralized location. (M2/M3/M4) They are used for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in hospital and medical transport environments.

6. The new devices have the same technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities established the performance, functionality, and reliability characteristics of the new devices with respect to the predicates. Testing involved system level tests, integration tests, environmental tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence. The results demonstrate that the network software interface functionality meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 2000

Mr. Dave Osborn
Regulatory Affairs Engineer
Agilent Technologies, Inc.
Health Care Solutions Group
3000 Minuteman Road
Andover, MA 01810-1099

Re: K001057
Agilent Technologies Information Center Central Station Software Release C.0 and M3000A / M3046A Patient Monitoring System M2/M3/M4 Revision C
Regulatory Class: III (three)
Product Code: DSI
Dated: March 31, 2000
Received: April 3, 2000

Dear Mr. Osborn:

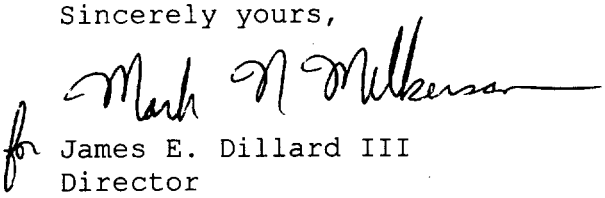
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001057

Device Name: Agilent Information Center Software, Release C.0

Indications for Use: For central monitoring of adult, pediatric, and neonatal patients; and where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

Device Name: Agilent M2/M3/M4 Compact Portable Patient Monitor, Revision C

Indications for Use: Intended for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in hospital and medical transport environments.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use**

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Mark N Milhorn

for (Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001057